UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

In Re: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION

MDL NO. 2740

SECTION "N" (5)

THIS DOCUMENT RELATES TO ALL CASES

DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFFS' MASTER LONG FORM COMPLAINT

Plaintiffs fail to plead the elements of their claims. Additionally, the Master Complaint does not provide the individual Defendants with adequate notice of specific conduct that allegedly warrants liability. Plaintiffs do not sufficiently address this failure in their Opposition.[1] Instead, they ask the Court to apply a lower pleading standard because this is a Multidistrict Litigation ("MDL"). But that is not the law, or a common practice in MDL courts.

First, federal pleading requirements apply equally in MDLs—no authority states otherwise. Second, Plaintiffs have not satisfied those requirements. Plaintiffs' boilerplate and repetitive Master Complaint (1) fails to adequately give Defendants notice of their alleged wrongful conduct; (2) fails to plead any plausible facts regarding causation; (3) fails to cite a single relevant express statement by any Defendant that was misleading (required for both strict liability for misrepresentation and breach of express warranty); and (4) fails to plead allegations

[1] *See* Memorandum in Opposition to Defendants' Motion to Dismiss Plaintiffs' Master Long Form Complaint (Rec. Doc. 704) ("Pls.' Opp.").

of fraud with particularity. For these reasons, Plaintiffs have not stated a claim upon which relief can be granted and their Master Complaint[2] should be dismissed. *See* FED. R. CIV. P. 12(b)(6).

I. The Federal Rules of Civil Procedure Apply Equally Here

Plaintiffs repeatedly argue that the Court should relax the federal pleading requirements and that the Master Complaint should be interpreted "in light of [its] administrative purpose."[3] But that reasoning—which surfaces in all of Plaintiffs' arguments—has been squarely rejected by MDL courts and criticized as a significant problem with MDLs. The *Zofran* MDL court, for example, recognized that the "creation of an MDL proceeding does not suspend the requirements of the Federal Rules of Civil Procedure, nor does it change or lower the requirements of those rules." *In re Zofran (Ondansetron) Prods. Liab. Litig.*, No. 1:15-md-2657, 2017 WL 1458193, at *5 (D. Mass. Apr. 24, 2017). Likewise, in the Obtape MDL, the court noted its concern that MDLs produce incentives to file cases and claims that "otherwise would not be filed if they had to stand on their own merit as a stand-alone action." *In re Mentor Corp. Obtape Transobturator Sling Prods. Liab. Litig.*, No. 4:08-md-2004, 2016 WL 4705827, at *1 (M.D. Ga. Sept. 7, 2016).

No authority—statute, rule, or case—"relaxes" the Federal Rules' pleading requirements in MDLs. Nor does any authority morph all MDL master and short form complaints into "administrative" documents that should not be ruled on by the court. Though some MDL courts have decided not to make Rule 12(b)(6) determinations, they have done so because of the unique circumstances and timing of those MDLs, not because pleadings in all MDLs are

[2] *See* Plaintiffs' First Amended Long Form Complaint and Demand for Jury Trial (Rec. Doc. 689) ("Am. Compl.").

[3] *See, e.g.*, Pls.' Opp. at 8 (citing "special concerns" for MDL courts); *id.* at 11 (claiming conclusory allegations of causation are sufficient "in light of the purpose the Master Complaint"); *id.* at 17 (claiming that Rule 8's pleading requirements for breach of express warranty are "relaxed" and that Plaintiffs should be given "substantial leniency"); *id.* at 22 (claiming that Plaintiffs cannot state fraud allegations with traditional particularity given the "administrative purposes of a Master Complaint").

"administrative." *See In re Nuvaring Prods. Liab. Litig.*, No. 4:08-md-1964, 2009 WL 4825170, at *1 (E.D. Mo. Dec. 11, 2009) (declining to rule on hundreds of individual Rule 12(c) and 12(b)(6) motions where defendant had answered individual complaints months before the master complaint was filed, "neither [the] Plaintiffs nor [the Court] intended the master complaint to be subject to pleadings challenges," and the Court had vacated its previous order requiring the master complaint to be filed at all.). If the Federal Rules' pleading requirements are to have any meaning at all, they must be applied and enforced by the MDL court "at the relative outset of a proceeding, not after months or years of discovery and motion practice." *In re Zofran*, 2017 WL 1458193, at *5; *see also In re Mentor Corp.*, 2016 WL 4705827, at *2 (imploring MDL courts to consider approaches to weed out non-meritorious claims "early, efficiently, and justly").

Contrary to Plaintiffs' suggestion, the *Trasylol* and *Zimmer* MDL courts did not unilaterally create a new "substantial leniency" pleading standard for MDL plaintiffs. In fact, citing those very cases, the *Zofran* MDL court rejected the idea that the pleading requirements for MDL plaintiffs are somehow different than in other cases, noting that the "complaint" in an MDL is comprised of *both* the master and short form complaints. *In re Zofran*, 2017 WL 1458193, at *5–6 ("To the extent plaintiffs suggest that [the pleading requirements] should not be enforced by the [MDL] court, as it may require individualized determinations as to the adequacy of individual complaints, that assertion is likewise incorrect.") (citing *In re Trasylol Prods. Liab. Litig.*, No. 08-md-1928, 2009 WL 577726, at *9 (S.D. Fla. Mar. 5, 2009); *In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, No. 11-cv-5468, 2012 WL 3582708, at *4 (N.D. Ill. Aug. 16, 2012)).

Plaintiffs also blur the distinction between case-specific allegations (those that are specific to a particular case) and defendant-specific allegations (those that are specific to a

defendant but could be common across cases). Plaintiffs' attempt to interpose a non-existent "leniency" standard ignores the reality that whether in their Master or Short Form Complaints, Plaintiffs must satisfy the federal pleading requirements and plead all the necessary elements of their respective legal theories against the individual Defendants. That does not change when a case is in an MDL for coordinated proceedings. *See id.*

II. Plaintiffs Do Not Satisfy the Federal Rules' Pleading Requirements or Plead the Necessary Elements of Their Claims

First, the Master Complaint fails to connect any specific facts to any claims asserted by Plaintiffs, and improperly lumps distinct and unrelated Defendants together. Such a "shotgun" pleading does not provide Defendants fair notice, much less comply with Federal Rules of Civil Procedure 8 and 10. Second, Plaintiffs fail to allege plausible facts supporting causation. Third, the Master Complaint does not cite any express statement or promise made by any Defendant (a necessary allegation for both strict liability for misrepresentation and breach of express warranty). Finally, Plaintiffs fail to allege the "who, what, when, where, or how" that is required by Federal Rule of Civil Procedure 9(b) for their fraud-based allegations. Each of these deficiencies is fatal to their claims.

a. "Shotgun Pleading": Plaintiffs' Master Complaint Does Not Satisfy Pleading Requirements Because Its Vague and Irrelevant Allegations Do Not Put Defendants on Notice of Their Alleged Wrongful Conduct

Plaintiffs' Master Complaint is a shotgun pleading. A "typical shotgun complaint contains several counts, each one incorporating by reference the allegations of its predecessors, leading to a situation where most of the counts (i.e., all but the first) contain irrelevant factual allegations and legal conclusions." *Strategic Income Fund, L.L.C. v. Spear, Leeds & Kellogg Corp.*, 305 F.3d 1293, 1295 (11th Cir. 2002). Plaintiffs' Master Complaint does the same.

Paragraphs 4–219 consist of an extended narrative of "factual allegations," while Paragraphs 220–318 purport to set out eight "claims for relief."

In reality, however, those eight claims either incorporate *all* of the prior allegations by reference, or simply recite only the elements of common product liability causes of action in a boilerplate fashion. Worse yet, Plaintiffs lump all Defendants together. That does not provide individual Defendants with fair notice. And it does not comply with either Rule 8 or 10. *See, e.g.*, *Magluta v. Samples*, 256 F.3d 1282, 1284 (11th Cir. 2001); *Atuahene v. City of Hartford*, 10 F. App'x 33, 34 (2d Cir. 2001) ("By lumping all the defendants together in each claim and providing no factual basis to distinguish their conduct, [the] complaint failed to satisfy [the] minimum standard [of Rule 8]."); *see also Am. Resources Ins. Co., Inc. v. Evoleno Co., LLC*, No. 07-cv-0035, 2007 WL 8082473, at *3 (S.D. Ala. July 30, 2007) ("The vagueness of the factual allegations and which defendants they impact is exacerbated by the counts. Each purports to incorporate by reference every single preceding paragraph, despite the patent inapplicability of some and the dubious applicability of others.").

Plaintiffs' Master Complaint is deficient in both respects. It contains hundreds of paragraphs about "Defendants" generally, rarely distinguishing between them, and then incorporates every paragraph into each claim. This leaves each Defendant unable to determine what specific conduct allegedly supports liability under any particular legal theory.

Plaintiffs make no effort to address these problems in their Opposition. Instead, they ask for "substantial leniency" because they cannot plead "case-specific" allegations in the Master Complaint. *See* Pls.' Opp. at 8; *supra* Section I. The legal insufficiencies, however, have nothing to do with "case-specific" allegations. No case-specific analysis is required for Plaintiffs to plead the discrete conduct of each particular Defendant. Nor does it take any case-specific

analysis for Plaintiffs to plead a "short and plain statement" for each legal count. *See* FED. R. CIV. P. 8(a)(2). If Plaintiffs' theories do require case-specific allegations, Plaintiffs must still plead them, either in the Master or Short Form Complaint. *See In re Zofran*, 2017 WL 1458193, at *5-6.

Plaintiffs have thus failed to state a claim for relief and the Master Complaint should be dismissed. *See* FED. R. CIV. P. 12(b)(6); *Atuahene*, 10 F. App'x at 34.

b. <u>Failure to Plead Causation</u>: Plaintiffs Do Not Allege Facts that Plausibly Show Defendants' Conduct Caused Plaintiffs' Injury

Causation—both proximate and but-for—is a necessary element for each of Plaintiffs' legal theories. *See* Mot. to Dismiss at 7 (citing authority).[4] Like all allegations, allegations of causation cannot be bare and conclusory, but must be specific and plausible. *Id*. at 2–3; *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009). For pharmaceutical product liability cases, this means that a plaintiff cannot just state that a product caused an injury, or even that its manufacturer failed to warn of a particular risk. *See* Mot. to Dismiss at 7–8 (collecting cases); *see also Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008). Rather, a plaintiff must show that the defendant's conduct was the "producing cause" of the injury—that is, "that a proper warning would have changed the decision of the treating physician." *Id*. (quoting *Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1099 (5th Cir. 1991)). Determining whether that has been done is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. Plaintiffs have not made such a showing here.

[4] *See* Defendants' Memorandum in Support of Their Motion to Dismiss Plaintiffs' Master Long Form Complaint (Rec. Doc. 489) ("Mot. to Dismiss").

Plaintiffs' claim that they "would not have used" docetaxel is implausible. Plaintiffs each had cancer. *See* Am. Compl. at ¶ 5. Though undoubtedly different, each Plaintiff faced a severe enough disease that her physician advised, and she agreed, that the potentially life-extending benefits of docetaxel outweighed its listed and known side-effects including neutropenia, anemia, leukopenia, cardiovascular issues, neuropathy, edema, a host of possible allergic reactions, and death. Having accepted these risks and undergone treatment with docetaxel, Plaintiffs survived for months, years, or even decades—and counting.

On its face, then, Plaintiffs' allegation that they "would not have used" docetaxel is implausible because it suggests that not only Plaintiffs, but also their *treating physicians* would have foregone potentially life-saving treatment against the *possibility* of persistent hair loss. Plaintiffs' suggestion is that even a small risk of prolonged alopecia necessarily outweighs both the severe side-effects of chemotherapy and the consequences of cancer itself. Perhaps Plaintiffs acknowledge that this is implausible because instead of making such statements, they argue that their Master Complaint "implicitly" alleges causation. If those logical steps exist, Plaintiffs should articulate them. Not doing so only makes Plaintiffs' allegations insufficient as well as implausible. *Cf. Kelly v. Broward Sheriff's Office Dep't of Det.'s*, 560 F. App'x 818, 821 (11th Cir. 2014) ("bare and at best implicit factual allegations are insufficient to state a claim").

One way that Plaintiffs attempt to obscure this issue further is by vaguely stating that their physicians would have prescribed "effective alternatives" to docetaxel if differently warned. *See* Am. Compl. at ¶ 5; Pls.' Opp. at 12. This is likewise both insufficient and implausible. Docetaxel and other chemotherapy agents each have complex and distinct medical properties, risks, and benefits. Highly individualized cancer treatment regimens are studied and prescribed for their variable effects and efficacy based on myriad factors including, *inter alia*, a patient's

pre-existing health conditions (including age, menopausal status, other disease, etc.), cancer diagnoses and prognoses (including stage and type; tumor number, size, grade, and location; hormone receptor status; HER2 status; node positivity; metastasization; recurrence, etc.), previous cancer treatments (including surgery, radiation, etc.), and unique risk profiles for severe and life-threatening side effects. Many—if not all—Plaintiffs in this MDL underwent other extensive cancer treatment before, during, and after using docetaxel. This undermines causation both because other treatments may in fact have been the cause of any hair loss, and because past and concurrent treatments further limit the chemotherapy options for a particular patient. Again, Plaintiffs stop short of naming a specific treatment alternative offering as great or greater benefits with less risk for Plaintiffs within the rubric of the physician decision.[5] Thus, Plaintiffs' allegations are again both insufficient and implausible.

In sum, Plaintiffs' Master Complaint lacks factual allegations that, if proven true, would establish that absent Defendants' conduct, Plaintiffs would not have persistent hair loss. As such, Plaintiffs fail to state any claim upon which relief can be granted and their Master Complaint must be dismissed. *See* FED. R. CIV. P. 12(b)(6).

c. <u>Failure to Plead Express Misstatements</u>: Plaintiffs Do Not Allege Defendants Made Any Express Statements About Docetaxel and Persistent Hair Loss

Plaintiffs' Strict Liability for Misrepresentation and Breach of Express Warranty claims require Plaintiffs to point to some *express* language that constitutes the supposed misrepresentation or warranty. Plaintiffs do not point to any such statements here, and their claims must fail.

[5] Discussing causation, Plaintiffs again ask for leniency and again ignore their opportunity—and obligation—to provide individualized factual allegations through their Short Form Complaints. *See* Pls.' Opp. at 12 ("More specific allegations of causation could not, as a practical matter, be included in the Master Complaint."); *In re Zofran*, 2017 WL 1458193, at *6 (plaintiff-specific allegations "should normally be set forth in the individual short-form complaint.").

i. Strict Liability for Misrepresentation: Plaintiffs do not allege that Defendants made any express misrepresentations about the risk of persistent alopecia

In the minority of jurisdictions where strict liability for misrepresentation is even a cause of action, a plaintiff must allege "an affirmative representation of material fact regarding the character or quality of the product." *English v. Suzuki Motor Co., Ltd.*, No. 92-CV-195-G, 1997 WL 428565, at *7 (10th Cir. 1997) (unreported); *see also* RESTATEMENT (SECOND) TORTS § 402B (1965); Mot. to Dismiss at 11–12 (citing authority). Plaintiffs do not dispute that.[6]

Yet Plaintiffs do not cite any *express* statement by any Defendant about persistent alopecia that was supposedly misleading. Instead, they argue that Defendants "positioned [docetaxel] as [] safe and effective," "directed its U.S. sales force to misrepresent the safety and effectiveness of the off-label use of [docetaxel] . . . ," and made misleading statements about efficacy in advertisements. *See* Pls.' Opp. at 14 (citing Am. Compl. at ¶¶ 191–213). None of these are representations about persistent alopecia—the only injury alleged in these cases. There are no claimed injuries turning on efficacy or the off-label marketing of docetaxel. To state a claim for strict liability for misrepresentation, Plaintiffs cannot point to vague marketing statements about efficacy and off-label use; they have to allege that Defendants made misleading statements about *persistent alopecia*.

Nowhere in Plaintiffs' Master Complaint do they identify an express misrepresentation about the risk of persistent alopecia by any Defendant. As such, they have failed to state a claim

[6] Plaintiffs do not dispute that they must allege an express misrepresentation to properly plead a strict liability for misrepresentation claim. They seem to recognize what courts uniformly agree on: imposing *strict liability* on a pharmaceutical company for something that it did *not* say about a product would flip traditional tort law principles on its head and impose absolute liability. *See, e.g., Am. Safety Equip. Corp. v. Winkler*, 640 P.2d 216, 218–21 (Colo. 1982) ("Strict tort liability for misrepresentation does not impose an insurer status upon the manufacturer.").

for strict liability for misrepresentation, and that claim should be dismissed. *See* FED. R. CIV. P. 12(b)(6).

ii. Breach of Express Warranty: Plaintiffs do not allege that the sanofi Defendants made an express promise or warranty regarding Taxotere

As with their claim for strict liability for misrepresentation, to plead a claim for breach of express warranty, Plaintiffs must allege that the sanofi Defendants made a factual affirmation or promise about Taxotere. Plaintiffs do not dispute this point. They cannot, however, state a breach of express warranty claim by vaguely referring to a manufacturer's representations about "safety and effectiveness," "side effects," or "adequate[] test[ing]." *See* Am. Compl. at ¶¶ 196, 311–18. Courts, including this one, regularly dismiss complaints that are limited to those kinds of generic allegations. For example, in *Lussan v. Merk Sharp & Dohme Corp.*, this Court dismissed a breach of warranty claim against a drug manufacturer because the plaintiff "fail[ed] to offer any specifics as to [the manufacturer's] representations that could amount to a warranty." No. 17-cv-3086, 2017 WL 2377504, at *3 (E.D. La. June 1, 2017). In *Para v. Coloplast Corp.*, this Court also dismissed a breach of warranty claim against a drug manufacturer because the complaint did "not allege with specificity anything about the express warranty, including when it was made and who made it." No. 16-cv-14696, 2017 WL 24794, at *6 (E.D. La. Jan. 3, 2017); *see also Baldwin v. Star Scientific, Inc.*, 78 F. Supp. 3d 724, 740 (N.D. Ill. 2015) ("Plaintiff's fuzzy, non-specific, alleged 'statements' made by 'Defendants' concerning [the drug's] supposed benefits are too sketchy to support an express warranty claim against any Defendant.").

Such allegations do not provide fair notice to sanofi because breach of express warranty is a theory of contract law—not tort law—so the "language of the warranty itself dictates the obligations of the parties." *Baldwin*, 78 F. Supp. 3d at 740. Thus, allegations that can be copied-and-pasted into any complaint about any drug do not support a claim that a defendant made a

specific promise to plaintiffs about the drug at issue. *See Fisher v. APP Pharms. LLC*, 783 F. Supp. 2d 424, 431–32 (S.D.N.Y. 2011) (alleged warranty that drug was "safe for the use for which it was intended" was insufficient to state a breach of warranty claim because plaintiff did not allege "any specific words, promises or statements made by [the manufacturer . . .] that would create an express warranty"). Plaintiffs make cut-and-paste allegations here. They allege only generally that sanofi "expressly warranted" that Taxotere[7] was "safe and fit for use for the purposes intended." *See* Am. Compl. at ¶ 312. They make equally vague allegations about testing and side effects. *See id*.[8]

Alternately, Plaintiffs would blur the distinction between contract and tort law by reference to an extreme-minority and often-criticized tort theory[9] of "innovator liability."[10] This novel theory hinges on suppositions about the name-brand manufacturer's alleged duties to non-users and has nothing to do with contracts or breach of warranty. As such, Plaintiffs have no basis in fact or law to assert that the sanofi Defendants can warrant a product that it did not sell.

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[7] Plaintiffs also allege that sanofi expressly warranted products that it did not sell. *See* Am. Compl. at ¶ 312. As discussed below, that argument is unavailing.

[8] Plaintiffs also make vague and conclusory allegations regarding reliance. *See* Mot. to Dismiss at 16. Yet they have not attempted to show reliance in their Opposition. *See* Pls.' Opp. at 16. Instead, they again ask the Court to apply a new, relaxed pleading standard because they are in an MDL. The Court should decline this request. *See supra* Section I. Because Plaintiffs must still plead all the necessary elements of their cause of action—regardless of the fact that an MDL exists—and because they have failed to plead reliance here, their breach of express warranty claim should be dismissed.

[9] As even the case cited by Plaintiffs acknowledges: "every other circuit court of appeals to consider this issue [has] arrived at the same conclusion—a brand-name manufacturer cannot be held liable for injuries caused by the ingestion of a generic produced by a third party." *McNair v. Johnson & Johnson*, No. 15-1806, 2017 WL 2333843, at * 2 (4th Cir. May 30, 2017); *see also In re Zofran (Ondansetron) Prod. Liab. Litig.*, No. 1:15-md-2657, 2017 WL 3448548, at *6 (D. Mass. Aug. 4, 2017) (same).

[10] Under this theory, plaintiffs in a small minority of jurisdictions have argued that a brand-name manufacturer's duty of care extends to consumers who foreseeably rely on the name-brand manufacturer's product information when purchasing generics, the claims against whose manufacturers are otherwise preempted. *See McNair*, 2017 WL 2333843, at *3.

Plaintiffs have not pled the necessary facts to plausibly state a claim for breach of express warranty. Nor have they shown how a manufacturer of a product can warrant a product it did not sell or why Plaintiffs should be excused from pleading all the necessary elements of their claim, including reliance. Accordingly, Plaintiffs' Breach of Express Warranty claim should be dismissed.

d. Failure to Plead Fraud with Particularity: Plaintiffs Provide No Particularity on Their Fraud-Based Allegations

Federal Rule of Civil Procedure 9(b), which requires that allegations of fraud be plead with particularity, applies to the allegations underlying Plaintiffs' Strict Liability for Misrepresentation, Negligent Misrepresentation, Fraudulent Misrepresentation, Fraudulent Concealment, and Fraud and Deceit claims. To meet this particularity requirement, Plaintiffs must allege the "who, what, when, where, and how" of the alleged fraudulent conduct. *See, e.g.*, *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997); *see also* Mot. to Dismiss at 4, 17–18 (citing authority regarding particularity requirement). Plaintiffs do not dispute that their fraud allegations must be pled with particularity. Instead, they argue (1) that the particularity requirement only applies to allegations as opposed to causes of action—a distinction without a difference in Plaintiffs' "shotgun" Complaint; and (2) that they have met the pleading standard for fraud. Neither argument is persuasive.

First, Plaintiffs argue that their misrepresentation claims (both strict liability and negligence) are "not premised on allegations of fraud." *See* Pls.' Opp. at 18. To be sure, it is not at all clear from the Master Complaint what allegations Plaintiffs think support these legal theories, which is an entirely different reason their Master Complaint should be dismissed. *See supra* Section II.a. ("Shotgun Pleading"). But the conduct that supposedly supports Plaintiffs' strict liability and negligent misrepresentation causes of action, as plead by them, is allegedly

fraudulent in nature. Those allegations are therefore subject to Rule 9(b)'s particularity requirement.

For example, Plaintiffs claim that Defendants "negligently represented" that docetaxel "had been tested and was found to be safe and/or effective for its indicated use." *See* Am. Compl. at ¶ 249. They claim that Defendants' representations were negligent because "Defendants concealed their knowledge of . . . defects." *See id.* at ¶ 250. A claim that Defendants concealed their knowledge about the safety and efficacy of a drug is a fraud-based allegation—no matter how Plaintiffs characterize it. The same reasoning applies to Plaintiffs' strict liability for misrepresentation claim. The Master Complaint suggests, albeit poorly, that Defendants made vague "misrepresentations" about docetaxel, and that they did so intentionally. All legal theories based on those allegations are subject to Rule 9(b)'s pleading requirement, including strict liability for misrepresentation and negligent misrepresentation.

Second, Plaintiffs have not pled any of their fraud-based allegations with particularity under Rule 9(b)'s particularity requirement (*see* Pls.' Opp. at 21):

- **Knowledge and concealment of docetaxel's risks**. *See* Am. Compl. at ¶¶ 148–68.

  These paragraphs list studies and news articles, apparently to show that Defendants had knowledge of the risk of persistent alopecia. But there is not a single *factual* allegation that Defendants took some action to conceal those risks from the public, Plaintiffs' prescribing physicians, or Plaintiffs (aside from simple conclusory statements that it happened). To the contrary, studies and news articles would be publically available. Additionally, there are no particular allegations regarding who supposedly concealed those risks, when they concealed those risks, or how and where they allegedly concealed those risks.

- **"Misleading" and "fraudulent" marketing efforts**. *See id.* at ¶¶ 190–212.

  These paragraphs make factual allegations about sanofi's efforts to market Taxotere. And though they point to some specific statements made by sanofi in advertisements, none of those statements have anything to do with the risk of persistent alopecia—which

is the only injury alleged by Plaintiffs.[11] Nowhere in the paragraphs cited by Plaintiffs are there allegations that state who, what, when, where, and how Defendants supposedly misrepresented the risk of persistent alopecia.

- **Fraudulent "averments."** *See id.* at ¶¶ 259, 267, 270, 277, 284–96.

  These paragraphs restate Plaintiffs' conclusory allegations. There is not a single factual allegation about who made the supposed averments, much less what was said, or how, where, or when it was said.

Plaintiffs make numerous claims related to fraud. But they are not supported by factual allegations regarding underlying circumstances. Plaintiffs only recourse is to ask the Court—again—for "substantial leniency" and the "benefit of discovery" because this is an MDL. But MDLs are not created to send Plaintiffs on fishing expeditions. In fact, MDL courts routinely hold that "it is not appropriate to plead fraud claims in general terms, in the hope that discovery will reveal greater particularity." *In re Zofran*, 2017 WL 1458193, at *5 ("To the extent plaintiffs suggest that Rule 9(b) should not be enforced by the [MDL] court, as it may require individualized determinations as to the adequacy of individual complaints, that assertion is likewise incorrect."); *In re Ford Motor Co. Speed Control Deactivation Switch Prods. Liab. Litig.*, No. 05-md-01718, 2007 WL 2421480, at *10 (E.D. Mich. Aug. 24, 2007) (granting motion to dismiss nine counts of master complaint, including consumer fraud act claims for failure to meet 9(b) pleading requirement); *see also In re Ford Motor Co. Vehicle Paint Litig.*, MDL No. 1063, 1996 WL 426548, at *3 (E.D. La. July 30, 1996) (dismissing fraudulent misrepresentation claim in master complaint for failure to plead reliance).

[11] Plaintiffs allege that sanofi made misrepresentations about Taxotere's off-label uses and its efficacy as a chemotherapy drug. But Plaintiffs' cases are not about the off-label use of Taxotere, nor are they about efficacy. *See supra* Section II.c.i.

Plaintiffs' Strict Liability for Misrepresentation, Negligent Misrepresentation, Fraudulent Misrepresentation, Fraudulent Concealment, and Fraud and Deceit claims fail to plead the circumstances of the alleged fraud with particularity as required by Rule 9(b). Therefore, those claims should be dismissed for failure to state a claim upon which relief can be granted.

III. Conclusion

The federal pleading requirements apply with the same force in MDL proceedings as in individual civil actions. Here, Plaintiffs have not satisfied those requirements because (1) they failed to adequately give Defendants notice of the alleged wrongful conduct; (2) they failed to plead any plausible facts regarding causation; (3) they failed to cite an express misleading statement made by Defendants (required for both strict liability for misrepresentation and breach of express warranty); and (4) they failed to plead their allegations of fraud with particularity. Plaintiffs have thus failed to state a claim upon which relief can be granted and their Master Complaint should be dismissed. *See* FED. R. CIV. P. 12(b)(6).

Dated: August 24, 2017

Respectfully submitted,

/s/ *Douglas J. Moore*
Douglas J. Moore (Bar No. 27706)
IRWIN FRITCHIE URQUHART & MOORE LLC
400 Poydras Street, Suite 2700
New Orleans, LA 70130
Telephone: 504-310-2100
Facsimile: 504-310-2120
dmoore@irwinllc.com

Harley V. Ratliff
Adrienne L. Byard
SHOOK, HARDY& BACON L.L.P.
2555 Grand Boulevard
Kansas City, Missouri 64108
Telephone: 816-474-6550
Facsimile: 816-421-5547
hratliff@shb.com
abyard@shb.com

Counsel for sanofi-aventis U.S. LLC and Sanofi U.S. Services Inc.

/s/ *Lori G. Cohen*
Lori G. Cohen
R. Clifton Merrell
Evan Holden
GREENBERG TRAURIG, LLP
Terminus 200
3333 Piedmont Road NE, Suite 2500
Atlanta, Georgia 30305
Telephone: (678) 553-2100
Facsimile: (678) 553-2100
cohenl@gtlaw.com
merrellc@gtlaw.com
holdene@gtlaw.com

/s/ *Deborah B. Rouen*
Deborah B. Rouen
E. Paige Sensenbrenner
ADAMS AND REESE LLP
One Shell Square
701 Poydras Street, Suite 4500
New Orleans, Louisiana 70139
Telephone: (504) 581-3234
Facsimile: (504) 566-0210
debbie.rouen@arlaw.com
paige.sensenbrenner@arlaw.com

Counsel for Defendant Sandoz, Inc.

/s/ *Mark S. Cheffo*
Mark S. Cheffo
Mara Cusker Gonzalez
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Ave., 22nd Floor
New York, NY 10010
Phone: (212) 849-7000
Fax: (212) 849-7100
markcheffo@quinnemanuel.com
maracuskergonzalez@quinnemanuel.com

/s/ *John F. Olinde*
John F. Olinde (Bar No.1515)
Peter J. Rotolo (Bar No. 21848)
1100 Poydras Street
New Orleans, LA 70163
Phone: (504) 858-7000
Fax: (504) 585-7075
olinde@chaffe.com
rotolo@chafe.com

Counsel for Defendants Hospira, Inc., Hospira Worldwide, LLC, formerly doing business as Hospira Worldwide, Inc., and Pfizer Inc.

/s/ *Michael J. Suffern*
Michael J. Suffern
Jeffrey F. Peck
ULMER & BERNE LLP
600 Vine Street, Suite 2800
Cincinnati, OH 45202
Phone: (513) 698-5064
Facsimile: (513) 698-5065
msuffern@ulmer.com

Counsel for Defendant Actavis Pharma, Inc.

/s/ *John P. Wolff, III*
John P. Wolff, III, TA #14504
Nancy B. Gilbert, Bar #23095
Chad A. Sullivan, Bar #27657
Richard W. Wolff, Bar #34844
KEOGH, COX & WILSON, LTD.
701 Main Street
Post Office Box 1151
Baton Rouge, LA 70821
Phone: (225) 383-3796
Fax: (225) 343-9621
jwolff@keoghcox.com
ngilbert@keoghcox.com
csullivan@keoghcox.com
rwolff@keoghcox.com

AND
Via *Pro Hac Vice* Admission

/s/ *Julie A. Callsen*
Julie A. Callsen, TA, OH Bar #0062287
Brandon D. Cox, OH Bar #0089815
TUCKER ELLIS LLP
950 Main Ave., Suite 1100
Cleveland, OH 44113-7213
Phone: (216) 696-2286
Fax: (216) 592-5009
Julie.Callsen@TuckerEllis.com
Brandon.Cox@TuckerEllis.com

Counsel for Defendant Accord Healthcare Inc.

/s/ *Stanton E. Shuler, Jr.*
Stanton E. Shuler, Jr. (Bar No. 19152)
LEAKE & ANDERSSON LLP
1100 Poydras Street, Suite 1700
New Orleans, LA 70163-1701
Phone: 504-585-7500
Facsimile: 504-585-7775
sshuler@leakeandersson.com

/s/ *Geoffrey M. Coan*
Geoffrey M. Coan
Kathleen E. Kelly
HINSHAW & CULBERTSON LLP
28 State Street
Boston, MA 02109
Phone: 617-213-7000
Fax: 617-213-7001
gcoan@hinshawlaw.com
kekelly@hinshawlaw.com

Counsel for Defendant Sun Pharmaceuticals Industries, Inc. f/k/a Caraco Laboratories, Ltd.

/s/ *Erin M. Bosman*
Erin M. Bosman (Bar No. 204987)
Julie Y. Park (Bar No. 259929)
MORRISON & FOERSTER LLP
12531 High Bluff Dr.
San Diego, CA 92130-2040
Phone: 858-720-5100
Fax: 858-720-5125
ebosman@mofo.com
juliepark@mofo..com

Counsel for Defendant McKesson Corporation d/b/a McKesson Packaging Service

CERTIFICATE OF SERVICE

I hereby certify that on August 24, 2017, I electronically filed the foregoing with the Clerk of the Court using the ECF system which sent notification of such filing to all counsel of record.

/s/ *Douglas J. Moore*